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HOUSE SMALL BUSINESS

COMMITTEE

"The Importance of Technology in an Economic Recovery"

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STATEMENT BY

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ON BEHALF OF

The Advanced Medical Technology Association (AdvaMed)

Chairwoman Velazquez, Ranking Member Graves and members of the Committee, thank you for holding this important hearing today on the importance of technology in an economic recovery and the role that the Small Business Innovation Research (SBIR) grant program plays to promote job growth and medical research advances. My name is Will Rosellini, CEO of MicroTransponder Inc, a small medical device company located in Dallas, Texas.

MicroTransponder Inc. is a member of AdvaMed, the Advanced Medical Technology Association, which represents over 1,600 of the world's leading medical technology innovators and manufacturers of medical devices, diagnostic products and medical information systems. Over 70% of AdvaMed member companies are relatively small companies with sales of less than $30 million per year. The members are devoted to the development of new technologies that allow patients to lead longer, healthier, and more productive lives. Together, the members manufacture nearly 90 percent of the $86 billion in life-enhancing health care technology products purchased annually in the United States, and nearly 50 percent of the $220 billion in medical technology products purchased globally.

The medical technology industry is a critical component of the U.S. health sector. In addition to the profound contributions of medical technology to the health and well-being of the public, in 2006 the industry employed 357,700 workers; paid $21.5 billion in salaries; and shipped $123 billion worth of products. Taking into account the national multiplier impacts, the industry created (direct plus indirect plus stimulated impacts): 1.96 million jobs; payrolls that totaled $93 billion; and $355 billion in shipments/sales. However, we are not just a major contributor to the U.S. economy based on revenues and jobs. The devices we make also help patients stay healthier longer as well as recover more quickly after treatment, thus allowing patients to participate more fully at work and in the community.

The medical technology industry is fueled by intense competition and the innovative energy of small companies – firms that drive very rapid innovation cycles among products, in many cases leading new product iterations every 18 months. Our constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible.

Overview of MicroTransponder Inc.

The SBIR program has made it possible for MicroTransponder to develop treatments for chronic pain and other neurological disorders, including Tinnitus, Traumatic Brain Injury, PTSD, motor disorders, Autism, and others. Taken together, these conditions affect over 50 million people in the US and represent an economic burden of over $100 billion dollars annually.

Utilizing SBIR funding, Drs. Michael Kilgard and Navzer Engineer have recently collected preliminary data that suggest that our devices may soon be able to reverse the cause of a neurological disease. This disease severely affects 12 million people in the United States, and

500,000 veterans ---93,000 of whom have recently returned from Iraq. This disease is tinnitus. Tinnitus is a debilitating constant ringing sensation that originates in the brain itself. Tinnitus is caused by hearing loss, often from trauma related to explosions. The VA alone is projected to spend $1 billion annually by 2011 in tinnitus disability compensation alone. We expect to move our promising treatment for tinnitus into clinical testing in humans within 2 years. We treat tinnitus by implanting a small device near a nerve in the side of the neck. The device emits small electric pulses near the nerve, which sends a signal up to the brain to produce chemicals that allow the brain to reprogram itself. When a tinnitus patient receives this device therapy while listening to a series of auditory tones, the brain is able to reprogram itself to eliminate the painful ringing sensation of tinnitus. If successful in humans, our technology will be the first time a neurological disease has been reversed using medical devices. It is a very exciting time for us at MicroTransponder and it would not have been possible without the SBIR program.

I started MicroTransponder in 2006, while I was a graduate student in the neuroscience program at the University of Texas at Dallas (UT Dallas). I saw the potential of an invention by Dr. Larry Cauller. With funding from DARPA, Dr. Cauller had invented a wireless micron size nerve interface device aimed at interfacing nerves with prosthetic devices. However, I realized that this same wireless nerve interface device could also be applied more generally to the medical field, whereupon I started MicroTransponder to realize this vision. Using SBIR funding, our collaborator Dr. Michael Kilgard, also of UT Dallas has shown that our general approach can indeed be used to induce neuroplasticity in the brain. Dr. Kilgard's lab has shown that it is now possible to selectively alter brain function in a predictable and potentially therapeutic manner—it is this finding that may lead to an effective treatment for tinnitus and possible solutions for a host of other neurological disorders. More information on our neuroscience research can be found on our website www.microtransponder.com.

However, raising private money to bring this type of invention into the medical field is not easy. Even though I have an MBA, a JD, masters of neuroscience and have an entrepreneurial track record in the medical field, private funding was difficult to find. Our technology is so new that it represents a very high risk/high reward proposition and venture funding is difficult to obtain. However, the SBIR program is specifically designed to fund research on promising high risk projects. This type of risk is what leads to paradigm shifting discoveries.

In 2007, we received our first Phase 1 grant award from Joseph Pancrazio, program director of the extramural research program at NIH NINDS. Dr. Pancrazio not only approved our funding, but has remained inextricably interested and engaged in our research progress – he funded us truly believing that Dr. Cauller's neuroprosthesis technology will significant change the world someday. This award enabled us to obtain important data for the chronic pain indication. In the course of these efforts, we found that our technology could also be applied to a wide variety of nervous system based diseases, including tinnitus. This funding was part of the reason we were able to develop a robust research program at UT Dallas.

Last year, we applied for 5 SBIR grants and obtained funding for 3—the normal funding rate is

less than 1 out of 5, so this success rate spoke well about our technology and our team. We received support from program directors Roger Miller at NIH NIDCD and John Kusiak from NIH NIDCR, both believed that our technology could help the millions of patients suffering from neurological illness.

The SBIR grants serve a number of important roles in getting high risk/high reward companies off the ground. First they enable the companies to inexpensively test the feasibility of their technology and obtain additional funding if the technology does prove to be feasible. Secondly, when a company is able to show feasibility and garner additional SBIR funds, this provides an independent scientific validation of the company's approach and opens the door for venture capital and other private fundraising. For example, after receiving our first funds from the NIH, we were able to obtain additional funds from the Texas Emerging Technology Fund, which awarded us a $1.4 million grant. The combined funding has allowed us to obtain proof of principle laboratory data and finalize our prototype device. We are now preparing to enter clinical trials at the end of this year for treating chronic pain as well as possibly reversing tinnitus using medical device. This progress could never have been made without SBIR funding.

Without the SBIR program, many high risk/high reward technologies would not be developed and the public would have fewer new treatments for serious illnesses.

The Need for Alternative Funding Mechanisms Beyond SBIR/STTRs

There are a tremendous number of costs associated with any start-up company and SBIR funding only covers a small part of those costs. The program is limited in the funds that it provides and is very strict as to how that money can be spent. For example, those monies cannot support market research or the bulk of lawyer fees for intellectual property protection.

In addition, there is a long runway for obtaining funds. It can take one to two years to obtain funding. Even for a perfect proposal with clear scientific merit, there is a nine month time window between submission and receipt of funds. Those funds are very limited and we would suggest an increase in the amounts of funding for both Phase I and Phase II grants by 50%. That would help alleviate some of the burdens on small business. However, it is important that other sources of funds be available as well, since costs of device development continue to accelerate due to elevated FDA standards and higher healthcare industry costs.

There are three main sources for the large amount of capital that is needed to bring a new medical product to market. One is company revenues, another is VC funding, and a final one is to license the technology to or partner with an already established company.

Some small companies already have products on the market and use that revenue and experience to bring their SBIR supported products to market. Such companies do not have the capital to

support the risky R&D efforts that SBIRs support. The SBIR mechanism therefore allows these types of companies to develop innovative technologies that would otherwise not be developed.

A start-up company with no revenue other than SBIRs and a small seed amount of investment is in a different situation for getting their product to market. They will need considerable non-SBIR funds. These funds can come from VCs or a partner. Partnering is usually a preferred method of getting one's product to market because the start-up company does not have to develop the expertise needed in this area. However, not all products and not all companies are right for partnering. Many products may help patient populations that are very small and thus not as commercially attractive. In addition, and perhaps more importantly, in order to partner a technology, it is necessary to develop the technology to a later stage than SBIR funding alone can take it. This is where VC funding is needed.

The Impact of SBIR Eligibility Rules on VC Funding

A series of rulings from 2001 – 2003 by the Small Business Administration's Office of Hearings and Appeals resulted in the determination that small businesses that were majority-backed by venture capital investors were no longer eligible for SBIR grants. This regulation excludes many small medical technology companies from participating in the SBIR program – including many that have received SBIR grants in the past and are emblematic of the success of the program – even though these small businesses still have a tremendous need for assistance. This does not seem to be within the spirit of the original intent of the SBIR program, which is to help small businesses develop promising, early stage technologies.

It is far more attractive for a venture group to invest in risky technology if there is a track record of SBIR successes. This greatly reduces the risk of investment, however as the rules are today, many companies would have to give up their SBIR funding in order to obtain venture funding.

This is a catch-22 situation. In order to attract VC funding, a company must obtain SBIR funding first. However, they will lose that funding if the VC invests too heavily. This greatly reduces the amount of VC funds that can be raised, which reduces the probability of success and in the end reduces VC investments.

This regulation also makes it less likely that VCs will invest in a given company because they know that SBIRs are no longer possible. Start-up companies that have scientists from academia with solid track records of grant funding lose an important leverage tool for bringing in VC monies. This reduces overall investment and decreases the chance that many important technologies will not be developed.

Finally, the NIH is certainly interested in funding the very best ideas available. By removing many small companies from the pool of possible ideas, the current regulations remove some of the best ideas from consideration by the SBIR program.

Legislation to Restore SBIR Eligibility for Small Businesses

Addressing the VC funding issue is a concern to MicroTransponder and other small companies that rely on SBIR funding to develop new medical technologies for patients. By removing the VC funding mechanism from us, it decreases our chances of success. We may or may not eventually require VC funding on the order of over 50% ownership, however by not having that option, our overall probability of success is diminished.

Legislation for NeuroTechnology Research - National Neurotechnology Initiative Act (H.R. 1483)

Brain research has been underfinanced for decades relative to its economic burden on society. For example, the economic burden a prominent viral infection on the U.S. is approximately $40 Billion annually; and thus the federal research budget in 2008 was $18.2 Billion. In comparison, the economic burden of neurological diseases is approximately $100 Billion annually and the federal brain research budget for the NIH, DoD, and other sources is less than $10 Billion. Brain research is comparatively more expensive and many projects that show scientific merit to create treatments for neurological indications are currently going unfunded due to lack of resources dedicated to brain research. H.R. 1483 provides funds for neuroscience research to the 16 NIH agencies conducting brain research and SBIR companies in the field.

Within MicroTransponders's experience in the neurotechnology field, the biggest bottleneck is probably the FDA approval process. The FDA approval process costs far more and takes far longer for brain-related drugs, devices, and diagnostics than it does for other drugs, devices, and diagnostics. This means that when investors have a choice between funding two potential medical advances, it makes much more financial sense for them to fund the one that is not brain-related. As a result, treatments that could save and improve millions of lives are languishing. The key to solving this problem is not to make FDA's approval process any looser, but to get FDA the resources necessary to hire and train people who specialize in neurotechnology. AdvaMed is proud to partner with consumer groups, patient groups, and other industry organizations as a Member of the Alliance for a Stronger FDA, whose sole mission it to advocate for increased funding for the FDA. Getting the FDA more funding to hire the staff needed to specialize in neurotechnology, which will free up private capital for investment in companies like mine, which will allow us to expand.

The disincentives associated with the FDA approval process, as well as the difficulty and lack of SBIR funding, and the insufficiency in collaborations between the 16 institutes of NIH, the VA, and the DoD, all create deterrent forces against translational innovation. Many of these bottlenecks are addressed in a bill called the National Neurotechnology Initiative Act (H.R. 1483), sponsored by Representatives Kennedy and Ros-Lehtinen. Along with the Neurotechnology Industry Organization, I strongly support this bill as a way to ensure that our nation's basic research investments are effectively translated into diagnostics, treatments, and cures that save and improve lives, while generating jobs and moving our economy forward.

Conclusion

The United States spends a tremendous amount of money on basic research. We lead the world in research funding, in new discoveries, in scientific publications. Our research commitment is important and should be continued. But in order for this research to have a role in the economic recovery, it must be translated into applications. Only when new technology reaches the application stage does it begin generating jobs and improving people's lives.

Chairwoman Velazquez and Ranking Member Graves, we thank you for your leadership in the reauthorization of the SBIR program. We look forward to working with the Committee as legislation for SBIR reauthorization and for neurotechnology initiatives specifically move forward. We want ensure that small businesses will continue to drive medical innovation and develop promising new technologies for patients, especially as our nation seeks economic recovery. I'll be happy to answer any questions you may have.